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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,555	07/06/2001	Rod Ausich	4532660/19270	5010

7590

06/17/2003

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EXAMINER

PATTEN, PATRICIA A

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/900,555

Applicant(s)

AUSICH ET AL.

Examiner

Patricia A Patten

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) g.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-15 are pending in the application.

Applicant's election without traverse of the species of formic acid and potatoes in Paper No. 10 is acknowledged.

Applicant's Preliminary amendment was only entered in part for the following reason; the substitute pages of Specification are not accompanied by a marked-up version of these pages. The substitute pages of the Specification were not entered however will be entered upon the submission of a marked-up copy.

Further, a marked-up version of the claims was not received. The claims however, were entered in order to expedite examination of the application. Applicant is asked to also send a marked-up version of the claims.

Claim Objections

Claims 1-15 are objected to for the following reason:

Claims 1-15 either recite or depend upon a claim which recites 'between about .03 and 5.0 normality'. There is nowhere in the specification which describes a range of

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salt that is added to solution which would result in this normality range. Thus, this information lacks antecedent basis in the Specification.

Correction is necessary.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-15 either recite, or depend upon a claim which recites "in an amount to provide between 0.3 and 5.0 normality". This phrase is indefinite in that it appears that the claim is reciting that the solution itself is this normality. However, upon reading the Instant specification, it appears that Applicants intend for this to mean that the solution is 0.3 to 5.0 normality with regard to the sodium chloride content. The wording in the phrase, as it stands, may be interpreted to mean that the total normality of the solution, i.e., the normality of the formic acid *and* sodium chloride. Further, this range of normality was found to lack antecedent basis in the Specification (please see *supra*

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under 'Objections'). Therefore, it is suggested that the claim language be changed to '..and a salt in an amount to provide between about X_1 and X_2 normality with regard to said salt....', wherein X_1 and X_2 are normalities which possess antecedent basis in the Specification.

Claim 9 recites 'the filtering step'. This phrase lacks antecedent basis in the preceding claims in that the preceding claims did not specifically recite 'filtering'. It appears that Applicants may wish for claim 9 to depend upon claim 4 which specifically recites wherein the slurry is filtered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Ryan et al. (US 6,414,124 B1) or Ryan et al. (WO 99/01474) in view of Lunder (US 5,683,736).

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Ryan et al. . (US 6,414,124 B1) or (WO 99/01474) taught a method for isolating proteinase inhibitor II from potato tubers via extraction with a solvent (water/ethanol/.88% formic acid and 1.5 M NaCl), filtration via cheesecloth, heating the liquid portion to 70 °C, cooling, evaporation of ethanol, centrifugation and ultrafiltration via dialysis with 12-14 Kd MW cutoff (WO-p.9,. Example 1 and claims 1-6) and '124-col.5, Example 1).

The normality of the solution with regard to the NaCl content was therefore 1.5 N, within the claimed ranges of normality. The ratio of extraction solution to plant material was: solution/plant material = L/Kg = 0.225 L/.455 Kg which equals approximately 1:2, obviating claims to the solution/plant material ratio.

Ryan et al. did not specifically teach wherein the plant material was comminuted to between about 100 microns and about 1500 microns or 'less than about 100 microns' (claim 9) or wherein the extraction solution was 'alcohol free' (claims 2 and 15).

Lunder (US 5,683,736) taught a composition comprising black tea powder for use as an instant beverage (Abstract). Lunder taught that the tea leaves were "ground in order to increase their surface area for extraction" (col.3, lines 60-61).

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One of ordinary skill in the art would have been motivated have sheared the potato material to a small size such as 100-1500 μm in order to achieve increased extraction capability. It was clear from Lunder that grinding the tea leaves increased the extractable surface area. Although Lunder did not specifically disclose the Instantly claimed particle sizes, the ordinary artisan would have had a reasonable expectation that as the particle size decreased, the extractable surface area increased, thereby increasing the yield of water soluble material into the surrounding solution. The selection of particle sizes of about 100-1500 μm would have therefore been a judicious selection on the part of the ordinary practitioner, affording the potato material sufficient surface area for extraction.

It is deemed that blending the homogenate would not have raised the temperature to 90 ° C since no heat was added during the homogenization process according to Ryan et al. Thus, although it would have been expected that the temperature would have risen from room temperature due to friction created by the blender blades shearing the plant material, the ordinary artisan would not have expected that homogenizing in a blender would raise the temperature above 90 ° C.

Although Ryan et al. did not specifically teach wherein alcohol was *not* added to the extraction slurry, it is deemed that alcohol was not an essential to the yield of active constituents. As indicated by Ryan et al. " [addition of ethanol to the homogenate

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changes] the homoge nate from a paste to a liquid mixture which facilitates filtration" (p.9, lines 18-19). Therefore, the ordinary artisan would have expected that although the addition of ethanol to the extraction slurry would have made the slurry easier to filter, that the addition of ethanol would not have substantially changed the overall product especially lacking credible evidence to the contrary.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

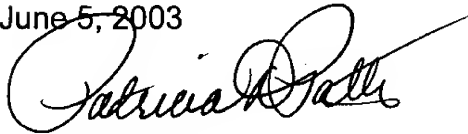
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback is on 703-306-3220 The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

June 5, 2003

A handwritten signature in cursive script, appearing to read "Patricia Patten", with a long, sweeping horizontal line extending to the right.

Patricia Patten